

**IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-1015 (GBW)
	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant.	)	
	)	
SAREPTA THERAPEUTICS, INC.,	)	
Defendant and Counter-Plaintiff	)	
	)	
v.	)	
	)	
NIPPON SHINYAKU CO., LTD. and	)	
NS PHARMA, INC., Plaintiff and Counter-	)	
Defendants.	)	
	)	

**LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM NIPPON  
SHINYAKU CO. AND NS PHARMA, INC. REGARDING OPPOSITION TO  
SAREPTA THERAPEUTICS, INC.'S MOTION TO AMEND**

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Dear Judge Williams:

Pursuant paragraph 5 of the Scheduling Order (D.I. 143), Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) submit this letter in opposition to Sarepta Therapeutics, Inc.’s (“Sarepta”) Motion to Amend its answer and counterclaims to add the University of Western Australia (“UWA”) to the instant action. Sarepta seeks to cure any perceived standing issue with its infringement counterclaims by joining UWA to the case.<sup>1</sup> However, this joinder comes months after Sarepta first proposed a stipulation to add UWA to the case (despite not being able to stipulate away a standing defect), long after discovery commenced, after contention and claim construction deadlines have passed, and after the parties have begun scheduling depositions. Joinder of UWA without requiring it to participate fully in discovery and commit to the contentions already submitted in the case would be contrary to the Federal Rules of Civil Procedure and disruptive to this Court’s Scheduling Order. Sarepta contends that upon joinder UWA’s discovery obligations should be “limited,” and makes no commitment that UWA’s joinder will not disrupt the case schedule. Mar. 21, 2023 Letter from Sarepta’s Counsel to the Court (D.I. 176). Joinder under Sarepta’s proposed limited discovery framework would unduly prejudice NS, and, thus, NS respectfully requests that the Court deny Sarepta’s Motion to Amend absent imposing the discovery obligations outlined herein on UWA.

### ***Background***

NS has worked in good faith with counsel for Sarepta and UWA to determine a path forward for joinder of UWA—the owner of all the patents that Sarepta alleges NS infringes—to cure any potential standing defect and allow UWA (who acknowledges it is a necessary party to NS’s invalidity declaratory judgment claim pertaining to the UWA patents (*id.* at 2)) to become a party to this litigation. NS does not take issue with the legal merits of joinder provided that UWA joins the case as a party who is subject to typical party discovery obligations. But Sarepta proposes that UWA be joined as a “limited” party that need not comply with typical discovery obligations. *See* Correspondence from Sarepta’s Counsel, Ex. A, Mar. 14, 2023 Email (“UWA is joining the case for the *limited purpose* of addressing any perceived standing deficiency in connection with Sarepta’s infringement counterclaims”) (emphasis added); *id.*, Mar. 17, 2023 Email (“But UWA is joining the case solely to address any perceived standing deficiency in connection with Sarepta’s infringement counterclaims, and *its discovery obligations should be reasonably commensurate with that limited involvement in the case*”) (emphasis added); D.I. 176 at 3 (arguing same). Thus, as a so-called “limited” party UWA appears unwilling to provide the types of information a patent owner and party would necessarily have—*e.g.*, information regarding conception and reduction to practice, inventorship, prior art, prosecution, and licensing.

Although counsel for Sarepta and UWA now tells the Court that “UWA intends to fully comply with its discovery obligations after it joins the case” (D.I. 176 at 3), the record developed during the parties’ meet and confers demonstrates the opposite. Indeed, when discussing joinder, UWA’s counsel made clear that UWA would not agree to comply with fundamental discovery obligations, including those expressly set forth in the existing Scheduling Order for this action such as timely serving (or joining in Sarepta’s) Rule 26 initial disclosures and infringement and

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<sup>1</sup> NS reserves its rights to challenge Sarepta’s standing in this case, and submits this letter not opposing conditional joinder without prejudice to its right to challenge standing.

invalidity contentions. *See* Ex. A, Mar. 15, 2023 Email (NS’s counsel proposing these conditions on agreement to not oppose joinder); *id.*, Mar. 17, 2023 Email (Sarepta’s counsel refusing to agree to these conditions). Based on UWA’s refusal to engage in full party discovery if joined to this case, and in light of the fact that discovery has been ongoing for over a year and core deadlines (including substantial completion of document production, service of initial infringement and invalidity contentions, and claim construction briefing) have passed, NS opposes Sarepta’s Motion to Amend.

***Unconditional Leave to Amend Should be Denied Because Otherwise NS Would Face Extreme Prejudice from UWA’s “Limited” Party Joinder and Refusal to Timely Participate in Discovery.***

Grant of leave to amend a pleading “is not automatic.” *ING Bank, FSB v. Am. Reporting Co., LLC*, 859 F. Supp. 2d 700, 703 (D. Del. 2012). Courts deny requests for leave to amend where, as here, the non-moving party would suffer undue prejudice. *See, e.g., Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273-74 (3d Cir. 2001); *cf. Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989) (“[P]rejudice to the non-moving party is the touchstone for the denial of the amendment.” (internal quotation marks omitted)). “Undue prejudice exists when an unfair burden has been placed on the opposing party.” *ING Bank*, 859 F. Supp. 2d at 703; *see also Bechtel*, 886 F.2d at 652 (stating to prove undue prejudice opposing party “must show that [they are] unfairly disadvantaged” by permitting amendment of pleading).

Here, allowing Sarepta leave to amend to add UWA as a party that is not subject to full discovery obligations would significantly prejudice NS. Sarepta should not be permitted to lie in wait, knowing of its potential standing issue, until the eve of claim construction and depositions to seek leave to add UWA as a party in what is clearly an effort to avoid having UWA participate fully in the discovery contemplated by the Court’s Scheduling Order. But this is precisely what Sarepta has done. Indeed, despite UWA’s claim that it “intends to comply fully with its discovery obligations after it joins the case,” (D.I. 176 at 3), NS requested confirmation and UWA’s counsel has made plain that UWA *will not* undertake the following obligations consistent with the existing Scheduling Order:

- Serve Rule 26(a)(1) Initial Disclosures and join the Protective Order within 14 days of joinder (D.I. 143 ¶¶ 1, 15);
- Agree that any discovery requests served on Sarepta through the date of joinder will be deemed to have been served on Sarepta and UWA, with UWA providing responses (or joining in Sarepta’s previously served responses) within 30 days of date of joinder (*Id.* ¶ 4);
- Serve core technical documents within 30 days of joinder (*Id.* ¶ 3(b));
- Adopt Sarepta’s infringement and invalidity contentions or serve its own contentions within 30 days of joinder (*Id.* ¶¶ 3(d) & (e)); and
- Formally join in Sarepta’s claim construction briefing within 10 days of joinder and confirm it has no intention to seek separate or additional oral argument time at the upcoming claim construction hearing (*Id.* ¶¶ 7-10).

See Ex. A, Mar. 15, 2023 & Mar. 17, 2023 Emails. Contrary to UWA’s plan, however, “[a] party cannot unilaterally absolve itself of its obligation to participate in discovery.” *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, No. CV 09-651-LPS, 2011 WL 13371929, at \*7 (D. Del. July 18, 2011).

UWA’s refusal to timely undertake the aforementioned discovery obligations if permitted to join this litigation unduly prejudices NS. For instance, UWA’s failure to agree to timely provide initial disclosures puts NS (who already served initial disclosures six months ago in accordance with paragraph 1 of the Scheduling Order) and UWA on unequal footing, “[un]level[ing]” “the playing field,” thereby automatically prejudicing NS who is left in the dark regarding information from UWA “needed to assess settlement, assist the parties in organizing and prioritizing their discovery, and prepare the case for trial.” *Givaudan Fragrances Corp. v. Krivda*, Civ. A. No. 08-4409 (PGS), 2012 WL 12919221, at \*2 (D.N.J. Sept. 28, 2012) (emphasizing importance of serving and supplementing initial disclosures to “avoid undue prejudice and surprise to the opposing party”).

Likewise, UWA’s refusal to respond to previously served discovery requests and contention that NS should be forced to use up its additional remaining discovery requests on UWA, places NS at an unfair disadvantage. This Court’s Scheduling Order contemplates a limit on interrogatories and requests for admission *per side*, recognizing there may be multiple parties per side. See D.I. 143 ¶ 4. Had UWA been joined as a party at the outset of the litigation or at any time before NS’s four sets of written discovery had been served, NS would have served the discovery it did to Sarepta as joint discovery requests to both UWA and Sarepta consistent with common practice in this District for multi-party patent cases.<sup>2</sup> Thus, it would be unfair and prejudicial to require NS to now duplicate its previously served discovery—and have such discovery count against the Court-ordered limits thereby undercutting the full scope of discovery contemplated in the Scheduling Order—merely because Sarepta waited until now to seek leave to cure a perceived standing issue that was known to Sarepta since the early stages of this case. Indeed, insofar as UWA is permitted to join the case, there is no reason for UWA, as owner of the asserted patents and university where the research leading to the UWA patent took place, to not answer previously-served discovery requests aimed at basic information—*i.e.*, conception and reduction to practice, prosecution of the asserted patents, prior art, and licensing.

Sarepta’s contention that it has “provided substantial discovery to NS, including the UWA laboratory notebooks” (Ex. A, Mar. 14, 2023 Email ¶ 1) fails to give any indication of what unique information and/or additional documents UWA itself may possess that is relevant and discoverable in the litigation should UWA be joined as a party and what information UWA should disclose in its initial disclosures. And UWA’s “facilitation” of production of lab notebooks (D.I. 176 at 3) falls far short of satisfying UWA’s independent discovery obligations should it become a party to

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<sup>2</sup> At the outset of the case, NS also would have considered serving UWA-specific and Sarepta-specific discovery requests, and NS reserves its right to do so if UWA is joined as party.

this litigation. Thus, UWA's refusal to commit to timely production of core technical documents is especially troubling and prejudicial to NS.

Further, although counsel for Sarepta contends that joinder of UWA is "unlikely to substantively affect the parties' claims or defenses," (*id.*) UWA's refusal to commit to timely joining in Sarepta's infringement and invalidity contentions or serving new ones creates significant concerns regarding prejudice to NS arising from joinder. Indeed, this leaves NS in the dark regarding what infringement theories it may need to defend against and what supposed validity theories it may face at trial and in expert reports. The parties are beginning to schedule depositions in the instant action, and it is essential to understand the full scope of validity and infringement theories before proceeding with depositions. If, as counsel for Sarepta and UWA says, UWA's joinder will not substantively affect claims or defenses, then UWA should quickly be able to join in previously served contentions so as not to delay the remainder of the case.

With the claim construction hearing just weeks away, UWA also refuses to commit to whether it will join Sarepta's claim construction briefing or whether it will seek additional argument time or separate argument at the hearing. It is unduly prejudicial to NS to face the potential for last minute changes to claim construction positions at the scheduled hearing if UWA joins the case. Potentially delaying the claim construction hearing (and thus needing to shift the entire schedule as a result) over a self-proclaimed "limited" party that declines to timely provide its claim construction positions is severely prejudicial to NS. *See generally Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 655 (3d Cir. 1998), *abrogated on other grounds recognized by Humana, Inc. v. Indivior, Inc.*, 2022 WL 17718342 (3d Cir. Dec. 15, 2022) (determining that duration of case and investment of resources into motion practice demonstrated undue prejudice from case delay associated with potential amendment).

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NS proposed reasonable conditions surrounding UWA's joinder to the instant action, which would ensure UWA is treated as a party without disruption of the current schedule. UWA and Sarepta refused, claiming instead that UWA should be treated a "limited" party with undefined discovery obligations. Although it remains unclear which party obligations UWA intends to undertake if joined to the litigation, based on representations during meet and confers, it is clear UWA refuses to even serve Rule 26 initial disclosures or join in or serve timely contentions in accordance with the Federal Rules and the Court's Scheduling Order. Permitting UWA to join the litigation without agreement to items detailed above would unfairly prejudice NS. Sarepta and UWA want to gain benefits of joinder by resolving any standing concerns while avoiding UWA having to undertake the necessary burden imposed on every United States litigant. They cannot have it both ways. Accordingly, NS requests the Court deny Sarepta's Motion to Amend absent the Court requiring UWA to comply with party discovery obligations including those enumerated above.

March 28, 2023

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Respectfully submitted,

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